REMARKS

Claims 1 and 12-37 constitute the pending claims in the present application. Claims 18-20, are withdrawn from consideration. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

The Examiner is advised that the following applications contain subject matter that may be related to the pending claims in the present application.

Application Serial Number	Attorney Docket Number
10/714,677	CDSI-P04-022
11/635,161	CDSI-P05-022
10/096,877	CDSI-P02-044
11/081,142	CDSI-P03-044

In particular, Applicants would like to draw the Examiner's attention to the fact that substantive examination may have occurred in these applications, and Applicants invite the Examiner to review any Office Actions that have issued or will issue in these cases. At the Examiner's request, we will provide copies of any Office Actions and/or responses to Office Actions that have issued in these applications. By bringing these applications to the Examiner's attention, Applicants do not waive the confidentiality provisions of 35 U.S.C. 122.

Double patenting. Claims 1, 12-19, and 21-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of 6,375,972. Applicants enclose herewith a terminal disclaimer thereby rendering this rejection moot. Applicants respectfully request reconsideration and withdrawal of this rejection.

Double patenting. Claims 1, 12-19, and 21-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 43, 46, 49, 50, 55, 58, 61, 63-67, and 70-74 of copending application 10/096,877. Applicants will address this rejection when it is no longer provisional.

Rejection based on 35 U.S.C. 102(b). Claims 1, 30-33, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (5,378,475). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The Office Action states that Smith teaches a sustained release drug delivery devices comprising an inner core or reservoir comprising the effective agent; a first coating layer, which is essentially impermeable to the passage of the effective agent; and a second coating layer which is permeable to the passage of said effective agent.

Claim 1 recites a sustained release drug delivery system comprising an inner drug core comprising an amount of an antiviral agent; an inner tube impermeable to the passage of said agent having first and second open ends and covering at least a portion of said inner drug core, wherein said inner tube is dimensionally stable and capable of supporting its own weight; an impermeable member positioned at said inner tube first end, said impermeable member preventing passage of said agent out of said drug core through said inner tube first end; and a permeable member positioned at said inner tube second end, said permeable member allowing diffusion of said agent from said drug core through said inner tube second end.

Smith teaches a sustained release drug delivery device which includes an inner core or reservoir comprising an effective agent, a first coating, and a second coating. Applicants assert that there is no teaching or suggestion of a device comprising an inner tube that is *dimensionally stable and capable of supporting its own weight*. In contrast, Smith describes a device that merely has an impermeable and a permeable *coating*. Applicants assert that a coating is not capable of supporting its own weight, whereas the inner tube of the pending claims is capable of supporting its own weight (see page 15, lines 12-14 of the specification).

Further, Applicants respectfully draw the Examiner's attention in particular to column 9, lines 1 to 34 of Smith which describe methods for making the disclosed devices. Specifically, Smith states that the devices may be made by "obtaining an effective amount of the agent and compressing the agent to a desired shape. Once shaped, a first *coating layer*... may be applied

directly ***in the form of a sheet or membrane*** to the outer surface of the agent.... Once the first *coating layer* is applied to the device, the second coating layer may be applied... ***by dipping the device one or more times in a solution containing the desired polymer***. Optionally, the second coating layer may be applied by ***dropping, spraying, brushing or other means of coating the outer surface of the device with the polymer solution***.... Given the active agent, and the composition of both the first coating and the second coating, one skilled in the art could easily make the devices of the present invention using ***conventional coating techniques***." (emphasis added)

Applicants assert that Smith does not teach all of the elements of the claim, in particular an inner tube that is dimensionally stable and capable of supporting its own weight, as recited in claim 1. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection based on 35 U.S.C. 103(a). Claims 1, 12-17, and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groenewegen (5,989,581) in view of Zaffaroni (3,948,254 ("'254")) and in view of Zaffaroni (3,854,480 ("'480")) and further in view of Visser (5,935,597). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The Office Action states that Groenewegen teaches a co-axial fiber having two ends which comprises a drug reservoir, an inner tube, and an outer layer covering the drug reservoir. The Office Action further states that Zaffaroni ('254) teaches a drug delivery device comprising two different walls surrounding said reservoir, wherein one wall is formed of a material impermeable to the passage of drug. The Office Action states that it would have been obvious to one of ordinary skill in the art to formulate and incorporate a drug delivery device comprising an impermeable layer or wall so as to prevent passage of an active agent, such as taught by Zaffaroni, within the drug delivery device of Groenewegen in order to provide for an effective drug release rate-controlling mechanism for the device. Finally, the Office Action states that Zaffaroni ('480) teaches a drug delivery system wherein suitable drugs include antivirals and Visser teaches drug delivery devices for treating viral infections which include nevirapine.

Pursuant to MPEP 2142, "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)."

Groenewegen describes a device comprising a thermoplastic polymer core and an "ethylene-vinylacetate copolymer skin" (column 4, lines 16-17). Applicants assert that there is no teaching or suggestion of a device comprising an inner tube that is *capable of supporting its own weight and is dimensionally stable*. In contrast, Groenewegen describes a device that merely has a copolymer skin on the polymer core. Applicants assert that a *skin*, like a coating, is not capable of supporting its own weight, whereas the inner tube of the pending claims is capable of supporting its own weight (see page 15, lines 12-14 of the specification).

Zaffaroni ('254) describes a device comprising a wall surrounding a reservoir containing a drug, wherein the wall is formed at least in part of a microporous material. Applicants assert that there is no suggestion or motivation to modify Zaffaroni such that the device comprises an inner tube that is *capable of supporting its own weight and is dimensionally stable* at all, much less an inner tube that also has first and second open ends.

Zaffaroni ('480) teaches a drug delivery device comprising an inner matrix and an outer polymeric membrane, wherein suitable drugs include antiviral drugs. Conceptually, this device is similar to Groenewegen, in that it has a drug-containing core surrounded by a skin or membrane. Applicants assert that there is no suggestion or motivation to modify Zaffaroni such that the device comprises an inner tube that is *capable of supporting its own weight and is dimensionally stable*, particularly since this element is entirely absent from both references.

Visser teaches a drug delivery device, such as a transdermal patch, for delivery of an antiviral medication. Applicants assert that Visser provides no suggestion or motivation to modify Zaffaroni such that the device comprises an inner tube that is *capable of supporting its own weight and is dimensionally stable*.

Applicants assert that *none* of the references, alone or in combination, teach all of the elements of the claim, in particular an inner tube that is dimensionally stable and capable of supporting its own weight, as recited in claim 1.

Rejection based on 35 U.S.C. 103(a). Claims 1, 12-17, and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni (3,948,254) in view of Zaffaroni (3,854,480) and further in view of Visser (5,935,597). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

The Examiner has stated that it would have been obvious to one of ordinary skill in the art to incorporate the antiviral agents of Zaffaroni ('480) in the device of Zaffaroni ('254) and the expected result would be a highly effective, controlled rate-release drug delivery device. The Examiner has further stated that it would have been obvious to one of ordinary skill in the art to incorporate the antiviral agent of Visser within the devices of Zaffaroni ('480) and Zaffaroni ('254).

Applicants assert that, for the reasons discussed above, the device of the pending claim is patentable over Zaffaroni ('480) and Zaffaroni ('254), in view of Visser. Applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. 103(a). Claims 1, 12-17, and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (5,378, 475) in view of Visser (5,935,597). Applicants traverse this rejection to the extent it is maintained over the claims as amended.

Applicants assert that, for the reasons discussed above, the device of the pending claim is patentable over Smith. The Examiner states that it would have been obvious to one of ordinary skill in the art to incorporate the antiviral agent of Visser within the device of Smith. Applicants assert

that, for the reasons discussed above, the device of the pending claim is patentable over Smith; therefore a device of the pending claims that comprises nevirapine is also patentable over Smith. Visser offers nothing to teach or suggest the inner tube as recited in the pending claims. Applicants respectfully request reconsideration and withdrawal of this rejection.

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. Applicants believe no fee is due with this response, aside from the Petition for Extension of Time. However, if an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. CDSI-P01-030 from which the undersigned is authorized to draw.

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Respectfully submitted,

By _____

Maya Escobar, Ph.D.
Registration No.: 56,346
ROPES & GRAY LLP
One International Place
Boston, Massachusetts 02110
(617) 951-7000
(617) 951-7050 (Fax)
Attorneys/Agents For Applicant